REMARKS

In the Office Action dated February 11, 2008, claim 11 was rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Claim 11 has been cancelled, and therefore this rejection is moot.

Claims 1-11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Teshima in view of Thangaraj et al.

Claim 1 has now been cancelled, and has been replaced by independent claim 12. Under the assumption that the Examiner may still consider the Teshima and Thangaraj et al references to be relevant to the subject matter of independent claim 12, Applicants provide arguments below in support of the patentability of claim 12 with regard to the teachings of those references.

First, in substantiating the rejection of previous claim 1, the Examiner characterized the use of the term "clinical study" as being non-functional, but also cited the Thangaraj et al reference if the term "clinical study" is used as functional language.

In response, Applicants submit that the term "clinical study" as was used in claim 1 (the term "medical clinical study" now being used in claim 12) is a term that has a well-understood and defined meaning in the field of medical data collection. As explained in the introductory portion of the present specification, a clinical study (also sometimes called a clinical trial) is a type of medical investigation that is intended to collect large amounts of data from a large patient population, for assessing various types of medical questions, such as the efficacy of a specific medical treatment regimen or drug, side-effects associated with a specific medical treatment regimen or drug, symptoms associated with a particular pathology or

disease, etc. Such studies or trials are usually initiated by being commissioned by a particular research group, either public or private, that has an interest in collecting data for a specific medical purpose. Such studies or trials may be done purely for research purposes, or may be done for commercial purposes, such as for achieving FDA approval for a new medical device or drug, or a new use of an existing device or drug.

Because of the necessity of obtaining a large amount of data from a large number of participants, it is usually the case that entry of the data for computerized analysis in the clinical study will occur at a large number of input locations (typically computer workstations). It is also typical, particularly in large hospitals or clinics, that the large number of patients in such hospitals or clinics will include participants in many different clinical studies. It is a problem, when a particular patient is treated at such a hospital or clinic and patient data associated with the treatment must be entered into a data base, to recognize that a particular patient is, in fact, a participant in a particular study. It is often necessary for the person in charge of entering data to scroll through a large number of clinical studies in which a hospital or clinic is participating as a sponsor, or as a participating facility, so that the "right" clinical study can be matched to the "right" patient, whose data are currently being entered into the databank.

It is also a problem, because the data will necessarily be entered into the databank for a particular clinical study at a number of different locations, that different locations may have differently-appearing data entry menus or displays or formats, and therefore the data may be entered in different ways, in different menu fields, at different locations.

As noted above, these problems are identified and discussed in the introductory portion of the present specification. An Information Disclosure Statement is being filed simultaneously herewith, however, in order to make United States Patent No. 6,496,827 of record in the prosecution history. This patent is relevant for two reasons. The first is that the '827 patent provides clear evidence that the term "clinical study" is a well-understood term in the field of medical data collection, and has a clear meaning that sets the term "clinical study" apart from the generic problem of entering data into a computer for storage in a databank. All of the aforementioned problems that are unique to conducting a clinical study, and collecting and entering the necessary data therefore, are discussed, consistently with the above discussion, in columns 1 and 2 of this patent.

Applicants are using the term "medical clinical study" in the claims of the present application consistent with the well-known and well-understood meaning of that term in the field of medical data collection, as evidenced by the '827 patent. Moreover, Applicants are addressing the problem that is extensively discussed in the '827 patent in a manner differently from the solution proposed in the '827 patent, thereby demonstrating that a need still exists for solving the problems that are discussed in the '827 patent that are associated with entering data in the context of a clinical study.

New claim 12 claims a method to input and store data for a medical clinical study that overcomes the aforementioned problems. In the subject matter claims in claim 12, for a specific clinical study, an input platform program is automatically generated that includes a unique collection of input fields that are configured for entry of the data that is necessary for the specific medical clinical study. This unique

input platform program is distributed to each input location that will interface with patients participating in the specific medical clinical study. At each input location, when an interface with one of the patients occurs, who is a participant in the specific medical clinical study, a characteristic identifying the patient is entered into a computer system at that input location. Via this computer system, the unique input platform program for the specific medical clinical study is called and activated solely by entry of the aforementioned characteristic.

Therefore, the person entering the data does not have to spend time trying to associate the patient with a particular clinical study, since the appropriate input platform program is automatically called and retrieved simply and solely upon entry of the aforementioned characteristic of the patient. Moreover, since the input platform program has been uniquely designed for the specific medical study in question, the data will always be entered, at every input location, in the same way in the same fields, thereby greatly facilitating analysis of the entered data in the clinical study.

Moreover, claim 12 states that it is only by making entries in the respective data fields of the unique input platform program that data can be provided for the specific medical clinical study in question. This assures that data will not be entered for analysis in the clinical study in a manner or format that does not conform to the input platform operating program. Therefore, the method simultaneously ensures uniform entry of the data that are entered, and precludes occurrences of non-uniform entry of the relevant data, despite the fact that the data are being entered at numerous, different input locations via numerous different computer systems. the common feature that is shared by all of these different computer systems is that they

all have been provided with the aforementioned unique input platform program that has been designed specifically for the medical clinical study in question, and this unique input operating platform can be easily and unambiguously presented to the person making the data entries solely by entry of the patient characteristic.

With regard to the Teshima reference, as Applicants have previously argued that reference does not provide relevant teachings because it is not concerned with the details of clinical studies. The Teshima reference discloses only a clinical electronic acquisition system that allows a number of hospitals to be connected via the Internet for information exchange. Within each individual hospital, information exchange occurs via a local area network (LAN). Access to specific information occurs after a patient has been identified by means of a patient card, and after a user has been identified by an operator card. As described in column 8 of the Teshima reference, when successful logging into the system has occurred, the scope of information that can be retrieved or entered is determined, dependent on the access level indicated by the operator card.

Although this general medical information system described in the Teshima reference permits various types of medical information to be provided to an authorized user, as well as allowing new medical data to be entered into the system, the system disclosed in the Teshima reference does not support the implementation of a clinical study in any particular manner. There is nothing in the Teshima reference that allows any type of automatic matching between a patient and a specific medical clinical study, nor is there anything disclosed in the Teshima reference that would ensure that data for a specific medical clinical study are always entered into the computer system in the same way via the same input fields.

As noted above, the Examiner relied on the Thangaraj et al reference as, according to the Examiner, disclosing a method that includes generating an input platform program for the input of data in a clinical study, wherein the input parameters are customizable. This is described in paragraphs [0010] and [0011] of the Thangaraj et al.

Applicants submit that the Thangaraj et al reference does not go beyond the general teachings of the Teshima reference with regard to the uniform entry of data. The Thangaraj et al reference discloses an Internet-based management system for clinical studies that allows the users of a clinical study to communicate with each other via the management center. The management center allows users access to data and also processes data. There is no disclosure in the Thangaraj et al reference, however, as to how the input platform program is activated or selected, and therefore there is no disclosure in the Thangaraj et al reference to call and retrieve a unique input platform program for a specific medical clinical study solely by the entry of a characteristic of the patient who is participating in that specific medical clinical study.

Paragraph [0010] of the Thangaraj et al reference cited by the Examiner describes only the ability of a user to adapt his or her own requirements. The user of the clinical study, however, is not the patient.

Paragraph [0011] generally describes that the clinical study parameters can be defined in various ways.

Applicants also note paragraph [0075] of the Thangaraj et al reference, which only states that users are "defined" or "created" in the system.

Paragraphs [0082] and [0083], also noted by the Examiner, simply describe server and client computer relations, in the context of the network of the individual participants.

For the above reasons, therefore, Applicants respectfully submit that even if the Teshima system were modified in accordance with the teachings of Thangaraj et al, the subject matter of claim 12 still would not result.

Claims 2-10 add further steps to the novel and non-obvious method of claim 12, and therefore none of those claims would have been obvious to a person of ordinary skill in the field of collecting data for clinical studies under the provisions of 35 U.S.C. §103(a), based on the teachings of Teshima and Thangaraj et al.

Since a new independent claim is being presented after the final rejection, this Amendment is being filed simultaneously with an RCE. Entry and consideration of the present Amendment are therefore respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

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